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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,825	12/02/2005	Rachel Schneerson	4239-68226-07	1579
36218 7590 11/28/2007 KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE #1600 PORTLAND, OR 97204-2988			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/559,825	SCHNEERSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-22 and 34-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-22 and 34-62 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 7 September 2007, is acknowledged. Claims 1, 5, 8, 9, 10, 16, 18, 20, 21, 22, 34, 36, 37, 38, 39, 40, 41, 42, and 44 have been amended. New claims 47-62 have been added.
2. Claims 1-6, 8-22, and 34-62 are pending and under consideration.

### **Objection/Rejections Withdrawn**

3. The objection to claim 1 is withdrawn in light of the amendment of the claim.
4. The objection to claim 34 is withdrawn in light of the amendment of the claim.
5. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for "bovine serum albumin" and "mammalian serum albumins", is withdrawn in light of the amendment of the claim.
6. The rejection of claims 16-22 and 42-46 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of "carrier" is withdrawn in light of the amendment of the claims.
7. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for "comprises" is withdrawn in light of the amendment of the claim.
8. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for "comprises" is withdrawn in light of the amendment of the claim.
9. The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for "comprises" is withdrawn in light of the amendment of the claim.
10. The rejection of claim 37 under 35 U.S.C. 112, second paragraph, as being indefinite for "comprises" is withdrawn in light of the amendment of the claim.
11. The rejection of claim 38 under 35 U.S.C. 112, second paragraph, as being indefinite for "comprises" is withdrawn in light of the amendment of the claim.

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12. The rejection of claims 5 and 34-44 under 35 U.S.C. 112, first paragraph, scope of enablement for immunogenic conjugates comprising homopolymer polypeptides of  $\gamma$ PGA covalently linked to a carrier wherein the carrier is an analog or mimetic of the specific protein, is withdrawn in light of the amendment of the claims.

13. The rejection of claims 34-38 under 35 U.S.C. 102(b) as being anticipated by Alkan et al (*J. Immunology*, 107(2):353-358, 1971) is withdrawn in light of the amendment of the claims.

### **Rejections/Objections Maintained**

14. The objection to claim 5 is maintained. As newly amended, the claim obviates the original objection. However, the newly amended claim 5 now recites items a, b, c, d, e, f, g, h, I, j, k, l, o, and p. The listing does not contain an item listed as m or n.

15. The rejection of claims 1-6, 8, 9, and 11-15 under 35 U.S.C. 103(a) as being unpatentable over Alkan et al (*J. Immunology*, 107(2):353-358, 1971) and Welkos et al (*Microbiol.*, 147:1677-1685, 2001) in view of Pozsgay et al (*Proc. Natl. Acad. Sci., USA*, 96:5194-5197, 1999), is maintained.

Applicants argue that the cited reference combination would not have resulted in the claimed conjugate.

The examiner has considered applicants' argument, but does not find it persuasive. As newly amended, the claims now read on a conjugate comprising a *Bacillus*  $\gamma$ PGA linked to a carrier wherein said carrier.

As stated in the original rejection explanation, Alkan et al teach a conjugate of RAT and poly- $\gamma$ DPGA, but do not teach homopolymers of the  $\gamma$ DPGA. Welkos et al teach that vaccination with *B. anthracis* protective antigen (PA) results in antibody production following vaccination and that improved vaccines could therefore contain multiple antigenic moieties. The examiner

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apologies for inadvertently inserting  $\gamma$ DPGA into the cited reference explanation as  $\gamma$ DPGA is not mentioned, as correctly pointed out by applicants. However, Welkos et al do teach conjugates and multiple moieties resulting in successful antibody production and vaccination. As stated prior, Pozsgay et al teach optimal immunogenicity for conjugates when polymers of hapten moieties are utilized.

Thus, it would have been obvious to utilize homopolymers of  $\gamma$ DPGA conjugated to any carrier molecule in order to maximize the vaccination and antibody producing methods when immunizing with  $\gamma$ DPGA conjugates.

### **New Objections/Rejections Necessitated by Amendment**

#### **Claim Rejections - 35 USC § 103**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Newly amended claims 10- 16-22, 34-46, and newly added claims 49-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkan et al (*J. Immunology*, 107(2):353-358, 1971) and Welkos et al (*Microbiol.*, 147:1677-1685, 2001) in view of Pozsgay et al (*Proc. Natl. Acad. Sci., USA*, 96:5194-5197, 1999).

The claims are drawn to a conjugate comprising a homopolymer polypeptide of  $\gamma$ PGA linked to a carrier.

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Alkan et al teach conjugates comprising a *Bacillus* capsular  $\gamma$ PGA linked to RAT (Abstract, page 354, second column, second paragraph). Alkan et al do not teach homopolymers of the  $\gamma$ PGA.

Welkos et al teach that conjugates of *B. anthracis* protective antigen result in antibody production following vaccination and that improved vaccines could therefore contain these multiple antigenic moieties (Abstract; discussion, pages 1683-1684).

Pozsgay et al do teach that synthetic polymers of hapten moieties determines optimal immunogenicity for conjugates composed of linear polymers bound to a carrier protein (abstract; Methods section, page 5195; Table 2).

Thus, it would have been obvious to one skilled in the art to adapt the teachings of Pozsgay et al concerning polymeric forms of haptenic molecules to increase the immunogenicity of the conjugates of Alkan et al and couple the conjugates with multiple antigens, such as taught by Welkos et al, in order to maximize any anti-*Bacillus* responses.

### Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

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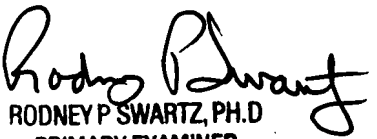
will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

November 14, 2007